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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/431,594	11/01/1999	JEFFERY J. WHEELER	16303-002430	8936
500 7590 06/14/2005 SEED INTELLECTUAL PROPERTY LAW GROUP PLLC 701 FIFTH AVE SUITE 6300 SEATTLE, WA 98104-7092			EXAMINER ZARA, JANE J	
			ART UNIT 1635	PAPER NUMBER

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/431,594

Applicant(s)

WHEELER ET AL.

Examiner

Jane Zara

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42 and 44-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42, 44-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office action is in response to the communications filed 4-4-05.

Claims 42, 44-75 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4-4-05 has been entered.

The declaration under 37 CFR 1.132 filed 4-4-05 is insufficient to overcome the rejection of claims 42, 44-75 based upon 35 U.S.C. 102 and 103 as set forth in the last Office action for the reasons set forth below.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Claims 42, 44-61, 63-75 are rejected under 35 U.S.C. 102(e) as being anticipated by Choi et al for the reasons of record set forth in the Office actions mailed 8-9-01, 5-16-02, 3-25-03, 12-15-03 and 9-30-04.

Claims 42, 44-61, 63-64, 67-75 are rejected under 35 U.S.C. 102(e) as being anticipated by Holland et al for the reasons of record set forth in the Office actions mailed 12-5-03 and 9-30-04.

Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Choi et al for the reasons of record set forth in the Office actions mailed 12-15-03 and 9-30-04.

Applicant's arguments and declaration filed 4-4-05 have been fully considered but they are not persuasive. Applicants argue that Choi and Holland do not properly anticipate (or that Choi does not render obvious) the instant invention because the method steps set forth by either Choi or Holland are distinct from those disclosed in the instant invention. Applicant also argues that the teachings of Choi or Holland would produce lipoplexes and not particles as claimed in the instant invention. Applicants rely on features, namely methods comprising steps that are distinguishable from Choi and Holland, that are not recited, and are not read into, the claims. Choi teaches compositions comprising bioactive agents encapsulated in lipid compositions comprising DOCAC, DOPE and conjugated lipids including PEG-ceramide (where ceramide has 8, 12 or 20 carbon) or PEG-phosphatidylethanolamine. Choi and Holland teach the inhibition of aggregation with the conjugated lipids claimed. The instant compositions are identical in composition to those taught previously by either Choi or

Holland. The claimed compositions are therefore presumed to have the same properties as those previously disclosed by Choi or Holland.

Applicants have provided evidence that the methods steps of Choi and Holland are different from the methods steps used in the instant disclosure to make the instant compositions. Applicants have also provided evidence that the compositions disclosed by Choi provide encapsulated particles, albeit at a lower percentage of encapsulation (see p. 6 of Wheeler declaration and Exhibit D). While the methods utilized in the instant disclosure appear distinguishable from those disclosed in the prior art, both Choi and Holland disclose the compositions claimed in the instant invention: Holland discloses compositions comprising a lipid selected from phosphatidylethanolamines (e.g. DOPE, col. 4), phosphatidylserines, ceramides, glycolipids and mixtures thereof, and further comprising a polyethyleneglycol-ceramide conjugate reversibly associated with the lipid, and whereby a PEG-ceramide conjugate ranges from 05 to 50 mole percent, and which compositions further comprise a cationic lipid selected from e.g. DOTMA or DDAC, and which compositions comprise amphipathic particles between 05-.45 microns, and which PEG-ceramides comprise saturated or unsaturated fatty acid carbon chains between two and 31 carbons in length (see col. 7-8). Choi teaches compositions for the delivery of bioactive agents, including nucleic acids, comprising DODAC, DOPEP and PEG-ceramide (col. 2-3, col. 24-26), and which compositions comprise conjugated PEG-ceramide or PEG-phosphatidylethanolamine, which ceramide has 8, 14 or 20 carbons (see Table 11), and which amphipathic particles are

between 89-103 nm, and comprise 5-10% PEG-ceramide, and which conjugated lipid inhibits aggregation of lipid containing, amphipathic particles.

The instant claims are drawn to compositions, not methods. Limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed.Cir. 1993). The compositions of the instant invention have identical chemical compositions to those disclosed by either Choi or Holland, and therefore cannot have mutually exclusive properties. (See *In re Spada*, 911 F2d 705, 709, 15 USPQ2d1655, 1658 (Fed. Cir. 1990).

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42, 44-75 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to compositions comprising nucleic acid-lipid particles of one or mixture of one or more cationic lipids, a conjugated lipids that inhibit aggregation of particles, and which compositions optionally further comprise additional, non-cationic

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lipids, and whereby the nucleic acids are encapsulated in the lipids and are resistant to nuclease degradation and the particles are inhibited from aggregating. The specification and claims do not adequately describe the broad genus comprising nucleic acid-lipid particles with the broad composition components claimed, whereby the nucleic acid is rendered resistant to nuclease degradation. The components comprising the compositions claimed, including any cationic lipid or combination of cationic lipids, conjugated lipids and non-cationic lipids encompass a broad array of compounds and specification and claims do not adequately describe the concise structural features that, together, render particle aggregation uninhibited, and render a nucleic acid encapsulated and resistant from degradation. Concise structural features that distinguish structures within the genus from those without are not adequately described in the instant disclosure for this broad genus claimed. One of skill in the art would reasonably conclude that Applicant was not in possession of the very broad genus claimed, which broad genus comprises compositions of nucleic acid-lipid particles comprising one or mixture of one or more cationic lipids, conjugated lipids that inhibit aggregation of particles, and which compositions optionally further comprise additional, non-cationic lipids, and whereby the nucleic acids are encapsulated in the lipids and are resistant to nuclease degradation and the particles are inhibited from aggregating.

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94

(December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is **703-872-9306**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (571) 272-0760. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JZ
6-9-05

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